

EC Declaration of Conformity

according to Directive 93/42/EEC (MDD) issued under the sole responsibility of the manufacturer

Manufacturer	STS Medical Group AD Industrial area Sokolovetz 2800 Sandanski- Bulgaria		
Product	Product name: Swabs American folded in cotton gauze or nonwoven sterile and non sterile REF: 2XXXX- 4XXXX-5XXXX-6XXXX-8XXXX Brand name: SECUSORB Description: Invasive surgical medical devices intended for transient or short term use. They can be used to control the microenvironment of a wound.		
Classification of Medical device	Class: IIa	Rule: 7	Conformity assessment route: Annex V
CE Marking	CE 0373		
Notified Body	Istituto Superiore Di Sanità Viale Regina Elena, 299, 00161-Roma, Italy		
EC Certificate	EC Certificate number: QPZ-1941-20 EC Certificate issue date: 06-Aug-2020		
Declaration	We, the manufacturer, hereby declare that the above-mentioned medical devices: <ul style="list-style-type: none">• Comply with the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC and 120 (3) of Regulation (EU) 2017/745• Are subject to a certified Quality Management System under supervision by a certification body. All supporting documentation is retained at the premises of the manufacturer.		
Declaration of Conformity	Revision	Place and Date	Approval by
MDD-DOC-EN-02-02	03	Sandanski, 10-Oct-2023	Anita Chacheva QM Group Manager
			Signature  